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September 8, 2009

Project Manager

Andrew Bain (SFD 6-2)
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Re: Comments on "Engineering Evaluation/Cost Analysis, Northeast Church Rock (NECR) Mine Site, Gallup, New Mexico," May 30, 2009

Dear Mr. Bain:

As you know, I have been conducting research in 20 chapters of Eastern Navajo Agency to determine whether exposures to uranium from anthropogenic and natural sources contribute to the high prevalence of kidney and other diseases. I am familiar with the NECR site as it is within our study area and we have conducted surveys as well as preliminary clinical laboratory assessments within that community. I understand from the above referenced EE/CA that EPA's preferred cleanup alternative for this site is to consolidate waste, transporting the most contaminated materials off-site to Idaho, and consolidating material between 2.24 and 200 pCi/g for storage in a lined, capped disposal cell (either existing or new) at the UNC mill site.

Before this decision is finalized, I want to add to the record a presentation of our results to date prepared for the Joint Meeting of the Indian Affairs/Radioactive and Hazardous Materials Committees on Thursday, September 10, 2009. Analysis of the survey data from our first 890 participants has shown that the likelihood of kidney disease and the related diseases of diabetes and hypertension is significantly increased when living in proximity to abandoned uranium mine (AUM) features, especially when weighted by the surface area of those features. In other words, the risk increases as a function of the combined surface area of abandoned waste in proximity to the home. This proximity to AUM factor is significant within the context of other more commonly recognized risk factors (also significant predictors in our model) including family history of disease, obesity, age, and level of education. Our data indicate that for individuals with equivalent family history, obesity, age, and education, the risk for these diseases can double in key regions where numerous large waste features are close to homes. For the NECR area, the likelihood of disease modeled on Slide 11 is nearly doubled based on the proximity factor. We were surprised to find that this factor is an even better predictor for autoimmune disease where the likelihood of disease increases more than 4-fold with gender the only other significant predictor. This study is the first in Navajo communities to look at exposure in the context of other risk factors, and to attempt to assess a variety of disease endpoints.

As I mentioned above, self-reported exposures also are significant predictors of disease, but generally have not been as good a predictor as the proximity factors we have derived (and refined) based on our geocoding of participants' homes in relation to the AUM inventory completed by the Army Corps of Engineers working with your office. At this point, we think that the geospatially derived proximity variables are actually surrogates for exposure, but are better predictors because many people do not realize they live near abandoned mines or waste features. As illustrated on slide 10, we think exposures may be underreported because nearly 25% of people are unaware of AUMs near their homes.

As we summarize on Slide 16, we still have several sources of data to collect in order to complete our analyses. However, given the current results summarized in the attached presentation, a Precautionary Approach would support the community's request that Alternative 2, removal of all contaminated materials for permanent off-site disposal, and relocation of all community residents for the duration of the clean-up would be prudent.

To review, the Precautionary Principle was adopted by the World Health Organization at the Basel Convention in 1989, signed by 100 nations. The adoption of the Principle was ratified at the UN Rio Conference in 1992, with the US as a signator. In 2000 the Precautionary Principle was formally adopted as the basis for decision-making by the EU. This Principle states that when uncertainty exists in the body of scientific information, decisions should be made that guarantee protection of health and the environment. This Principle continues to rely on sound science, but differs from alternative approaches to decision-making in how uncertainty is managed. In the NECR-affected communities

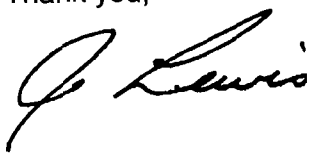
- those in proximity to NECR mine and the UNC mill have lived in proximity to large sources of uranium and other contaminants for more than 40 years;
- our data indicate residents in proximity to mines carry elevated uranium burdens compared to the US population as a whole and others within NM (Slide 13);
- contamination immediately surrounding dwellings was significant enough to initiate an emergency removal action in 2007;
- our results to date indicate this chronic exposure can significantly increase the likelihood of several diseases in these communities; and
- our confidence in our results is increased by the fact we have replicated in three successive analyses that proximity measured in many ways is a reproducible surrogate for exposure and significant predictor of disease.

Uncertainties remain in precisely characterizing exposures, and other disease end points that may be related but not analyzed in this study, such as cancer. However, our results are consistent with and logically extend recent basic science and epidemiological studies in the peer reviewed literature from the past several years that suggest uranium and other heavy metals often collocated with uranium waste are toxic at lower exposures and with broader outcomes than previously recognized. The uncertainties with respect to dose and specific mechanisms of action do not alter the results of current analyses that demonstrate an increased likelihood of disease for those living in this proximity to AUMs.

Off-site disposal would ensure these communities would no longer have to worry that vegetation could breach a cap, that a lining might breach and allow migration of contaminants to groundwater, or that a cap might erode and result in another pathway for exposure. The analyses in the EE/CA indicate that a certain level of risk to human health remains even at the 2.24 pCi/g clean-up level. A precautionary approach mandates minimizing any potential contaminant exposures that could add to the cumulative risk from the last 40 years, and any additional exposures resulting from the more than 1100 AUMs identified across the Navajo Nation which will remain even after this removal. This further strengthens the need for removal in situations where it can be accomplished. Had a Precautionary Approach been followed at any of several decision-points in the past, these residents would not have lived with the past 40 years of contamination, and we would not now be discussing strategies for dealing with the waste. Invoking such a policy now will ensure there are no regrets in the future.

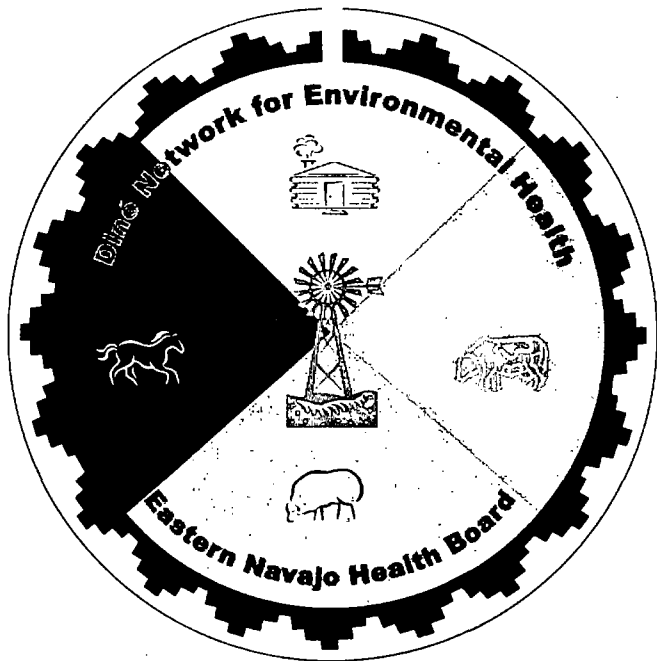
I would be happy to provide you with more information on details and interpretation of our analyses. Please feel free to contact me by email at jlewis@cybermesa.com or by telephone at (505) 272-4853.

Thank you,



Johnnye Lewis, Ph.D., DABT
Director, Community Environmental Health Program
PI, DiNEH Project

Encl: power point presentation: Compressed Indian Affairs Briefing September 2009d



Uranium Legacy Impacts on Health of Residents: DiNEH Project Update

Johnnye Lewis, Ph.D., DABT

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*Director, Novel Methodologies Research Component of the Clinical and Translational Science Center,
University of New Mexico-Health Science Center, College of Pharmacy*

*Principal Investigator (PI): DiNEH Project 's Navajo Uranium Assessment and Kidney Health Project
NIEHS/NIH funded Community-Based Participatory Research*

*Project Team: UNM: Mallery Downs, RN; Glenn Stark, Miranda Cajero, Bernadette Pacheco, Jeremy DeGroat,
Gabriel Huerta, Ph.D.*

*Southwest Research & Information Center: Chris Shuey, MPH (Co-PI), Sarah Henio-Adeky, Sandy Ramone, Teddy Nez
University of Texas, Houston: Don Molony, MD*

*(independent research in this presentation funded by NIEHS P30 ES-012072, R25 ES013208, & R01 ES014565
and M01-RR-00997)*

DiNEH Project research is reviewed and approved by

- ***Navajo Nation Human Research Review Board*** to ensure compliance with Navajo Nation Law, Respect for Navajo Culture and Protection of Navajo People, and by the
- **University of New Mexico Human Research Review Board, and**
- **Peer-Reviewed by the National Institute of Environmental Health Sciences of NIH**

Data presented reflect support from the following 20 chapters of the Eastern Agency of the Navajo Nation

- **Baca/Prewitt/Haystack, Becenti, Cassamero Lake, Church Rock, Crownpoint, Coyote Canyon, Iyanbito, Lake Valley, Littlewater, Mariano Lake, Nahodishgish, Ojo Encino, Pinedale, Pueblo Pintado, Smith Lake, Standing Rock, Thoreau, Torreon/Star Lake, Whitehorse Lake, White Rock**

We thank the 1050 members of those chapters who have participated in this research to date.

What are health concerns about uranium?

- **Uranium damages kidneys**
 - Higher the dose, more likely there will be damage
 - Caused by chemical properties of the metal, NOT by radiation
- **New Mexico populations already at risk**
 - High prevalence of diabetes & kidney disease
 - Early onset, increased severity
 - No studies in at-risk communities, or in children
- **Significant exposure potential**
 - Uranium & other heavy metals (also damage kidneys)
 - Naturally occurring and anthropogenic (human activity) sources
 - Soil, surface water, drinking water, plant/animal uptake

30 % of Navajos lack access to regulated water (compared to 0.6% of US as a whole, 12% for all tribes)

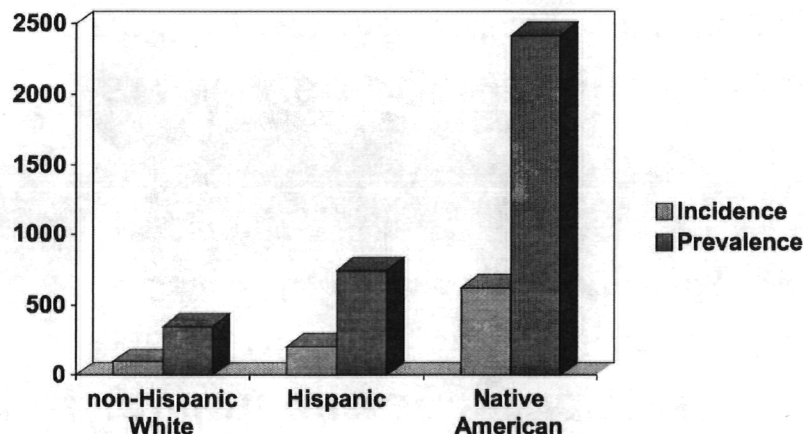


Children playing in contaminated arroyo, Church Rock, NM

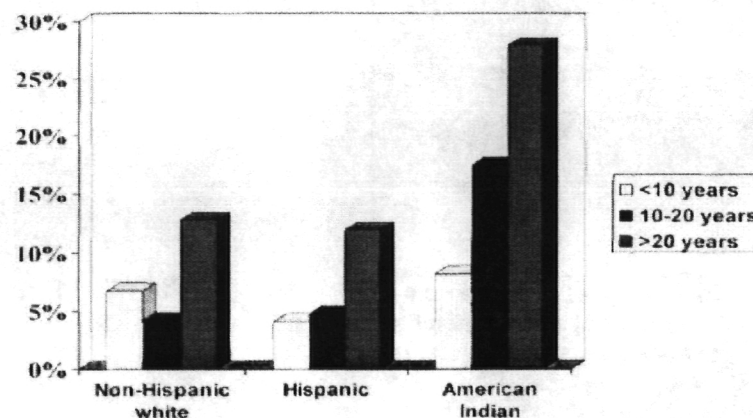


Health Disparities May Increase Sensitivity in At-Risk Populations: Two Examples

**End Stage Renal Disease
Disparities by Ethnicity/Race—
NM (2000) (per million; age
adjusted)**

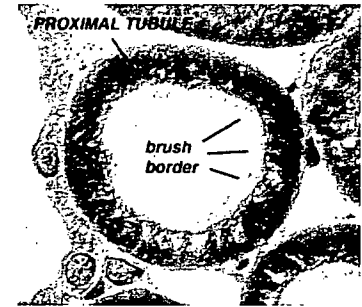


**Prevalence of Pneumoconiosis in
Underground Miners by
Ethnicity/Race Indicate Increased
Sensitivity in American Indians
(non-malignant respiratory disease, e.g.
fibrosis from deposition of particles)**



Major Concerns

Other Research Findings

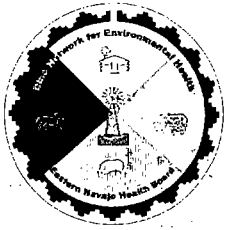


- **Linkage between heavy metals, hypertension, diabetes, kidney disease**
 - Lead linked to increased kidney disease in people with diabetes (VA Normative Aging Study) and hypertension (NHANES)
 - Recent laboratory studies show mechanisms for this effect (Tseng on arsenic/diabetes)
 - ATSDR showed biomarkers of exposure-related kidney damage persist after exposure stops in diabetics, but not in healthy individuals. Diabetes progression is accelerated.
- **Recent in vitro data also link uranium, as a metal, to cancer**
 - AFFRI (Miller); U of A (Ingram & Briehl); France (Théibault et al.,)
- **Results of medical monitoring at DOE's Fernald Uranium Processing Facility (Ohio):**
 - 2-4X higher rates of kidney diseases in those living within 5 mi. (not at-risk population)
 - Uranium primary exposure concern, but also radon, plutonium and other radionuclides
 - Also doubling of kidney cancer and melanoma, increased prostate cancer

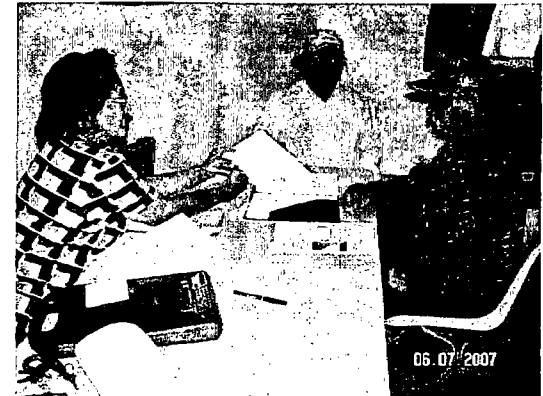
Don't Regulatory Standards Protect Health?

Evolution of health protective standards/guidelines

- **Groundwater limits have decreased by approximately an order-of-magnitude each decade since 1950 as scientific understanding improves**
- **Based on UNM/CEHP recommendation, NM WQCC decreased by >2 orders of magnitude 2003 (5 mg/L to 0.030 mg/L)**
- **Decision challenged and upheld by appellate decision (2006)**
 - *“the Commission properly amended the standard ..., credible scientific data existed in the record to support its action.”* The opinion further documented that the lowered standard was supported to be more protective of the public's health *“particularly because the state has a high Native American and Hispanic population, which is especially susceptible to those effects”.*



DiNEH Project

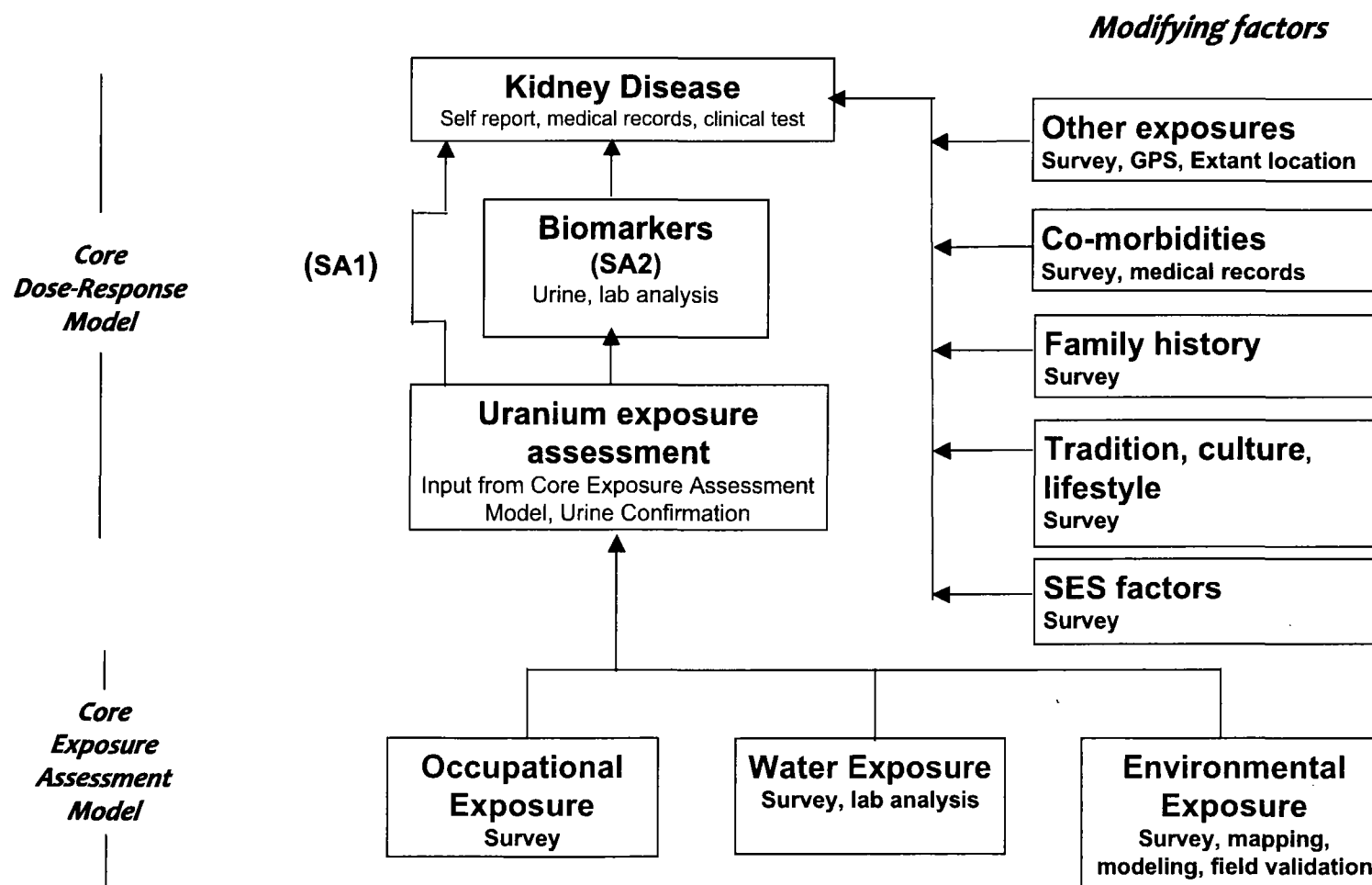


- **First community health assessment in uranium-impacted communities**
 - Specifically in a population at risk for kidney disease
- **Funded by National Institute of Environmental Health Sciences**
 - Collaboration with 20 Chapters in Eastern Navajo Agency, Crownpoint Service Unit of I H S, Southwest Research and Information Center, University of Texas. PI at UNM-HSC
- **Most comprehensive community-based assessment**
 - Includes a range of mine-impacted and non-impacted chapters
 - Comprehensive assessment of exposure, health, land use practices, and known risk factors
 - Relies on convergent validity, multilevel modeling, replication
 - Disease assessment from self-report, medical records, clinical screens, biomarker assays

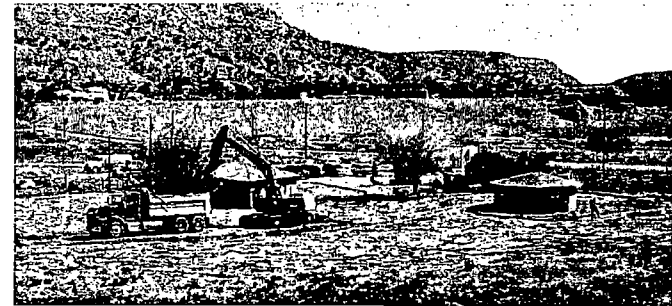
Multilevel model

Replication, Convergent Validity, Field Validation, Exposure confirmation

Kidney Risk Multi-level Model—Structure



Current status of DiNEH research



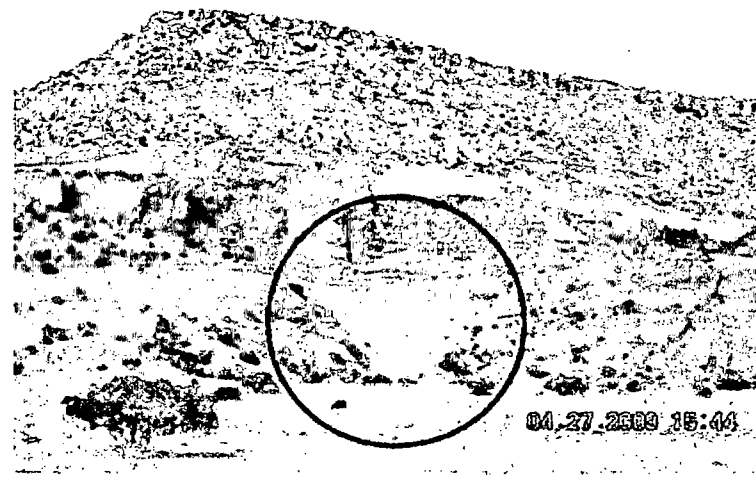
- **Survey (self-report) data**
 - demographics, water- and land-use practices, environmental and occupational exposure, and health status
 - completed for >1000 residents of 20 Eastern Navajo chapters
- **Water data not yet quantitatively integrated into modeling**
 - only yes/no for exposure

Year	# of Surveys	Analysis	Result
2007	300	qualitative/bar graphs	indicated hypertension, kidney disease, diabetes, and autoimmune disease increased as the number of mines in a chapter increased
2008	535	logistic regression. Model developed on random sample of 330, validated through prediction of remaining cases (deLemos thesis)	Analyzed kidney disease as an outcome. Showed living in proximity to mines was a significant predictor of disease, as well as commonly thought of risk factors like comorbidities, family history of the disease, obesity, age, and education. Autoimmune disease not modeled.
2009	890	logisitic regression and Bayesian Model Development	Replicated proximity as a significant predictor of hypertension, kidney disease, and diabetes. Proximity is best predictor of autoimmune disease.

Current refinement of our understanding

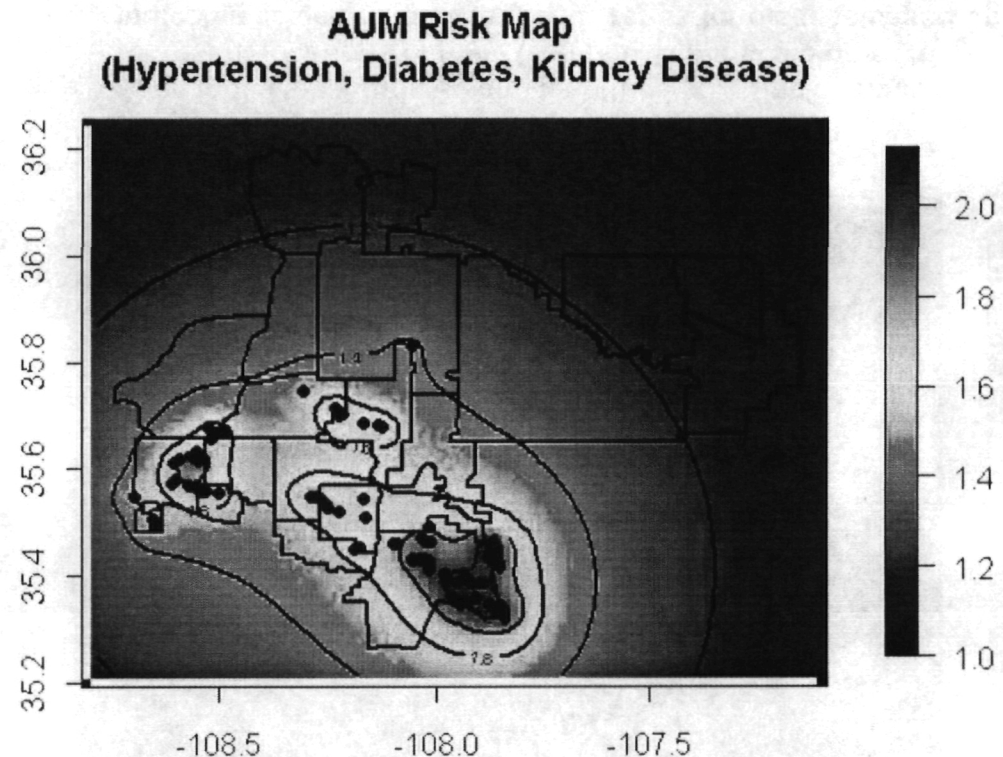
- **Best predictor: proximity to mine waste features weighted by areal surface of feature**
 - In other words -- for two mines of equal size, value is greater for closer mine, but a big waste pile 10 miles away may be less important than several smaller features within 1 mile of a home.
 - Why proximity rather than self-reported exposure?
 - 19-25% of respondents are unaware of whether or not they live near mines

Can You Tell These are Abandoned Uranium Mines?



Preliminary Analysis: Proximity to AUM Features Is a Significant Predictor of Hypertension, Diabetes and Kidney Disease

- Conditional models (n=890): proximity is a significant predictor of each disease, the 3 are linked to each other and improving the ability to predict any one improves the ability to predict the other two
- Family history of disease, obesity, age, and level of education are also significant predictors
- “Proximity” is calculated as the log of the sum of the inverse distances to all AUM features in the study area, weighted by the surface area of each feature



Axes indicate latitude (y) and longitude (x). Black circles represent locations of mine features. Color scale on right indicates scale of increasing odds ratios for diseases based on value of the weighted proximity variable. Map shows two distinct regions where odds of increased disease are increased more than 2-fold because of proximity to mines.

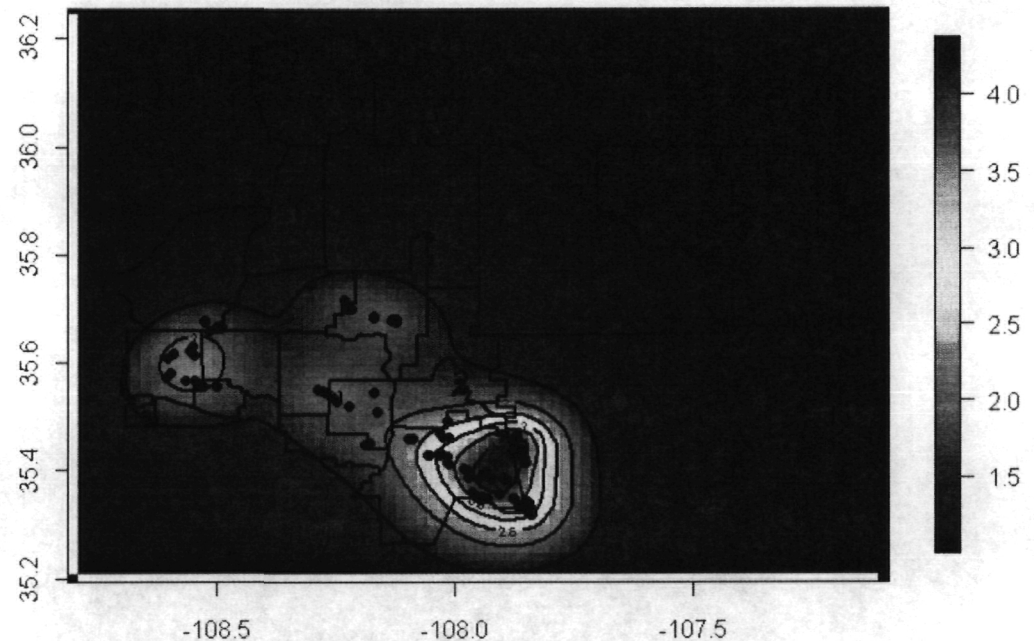
Preliminary Analysis: Proximity to AUM Features Is a Significant Predictor of Autoimmune Disease

- “Proximity” is calculated as the log of the sum of the inverse distances to all AUM features in the study area, weighted by the surface area of each feature
- Autoimmune disease reported less frequently in males
- Age, BMI, level of education, and self-reported exposure to AUM features not significant predictors
- Results consistent with estrogenic effects of U (Raymond-Whish)

AUM Model Summary Statistics

	Estimate	Std. Error	z value	Pr(> z)	Odds Ratios		
					Estimate	95% Confidence Interval	
(Intercept)	-3.63	0.31	-11.59	<0.0001			
Gender (Male)	-0.86	0.41	-2.08	0.0372	0.42	0.28	0.64
AUM Proximity	1.41	0.44	3.21	0.0014	4.12	2.65	6.41

AUM Risk Map (Autoimmune Disease)

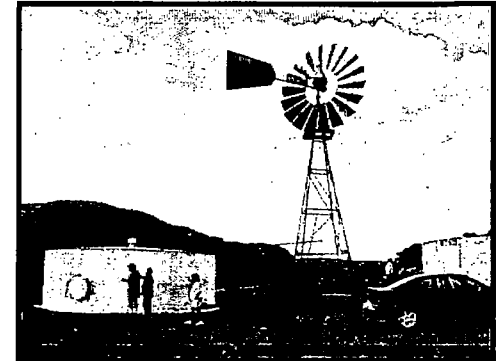


Axes indicate latitude (y) and longitude (x). Black circles represent locations of mine features. Color scale on right indicates scale of increasing odds ratios for disease based on value of the weighted proximity variable. Map shows a distinct region where odds of autoimmune disease are increased more than 4-fold because of proximity to mines.

DiNEH Exposure Data

Water

	DiNEH Project (October 2003 thru August 2009)
# Water Sources Sampled	108
# Water Sources Exceeding at Least 1 Primary MCL	17
USEPA Primary MCLs Exceeded (# water sources with exceedances in parentheses)	As (7), F (2), Gross Alpha (4), Hg (2), NO ₃ (2), Pb (1), Radium-226+228 (2), Se (5), U (9)



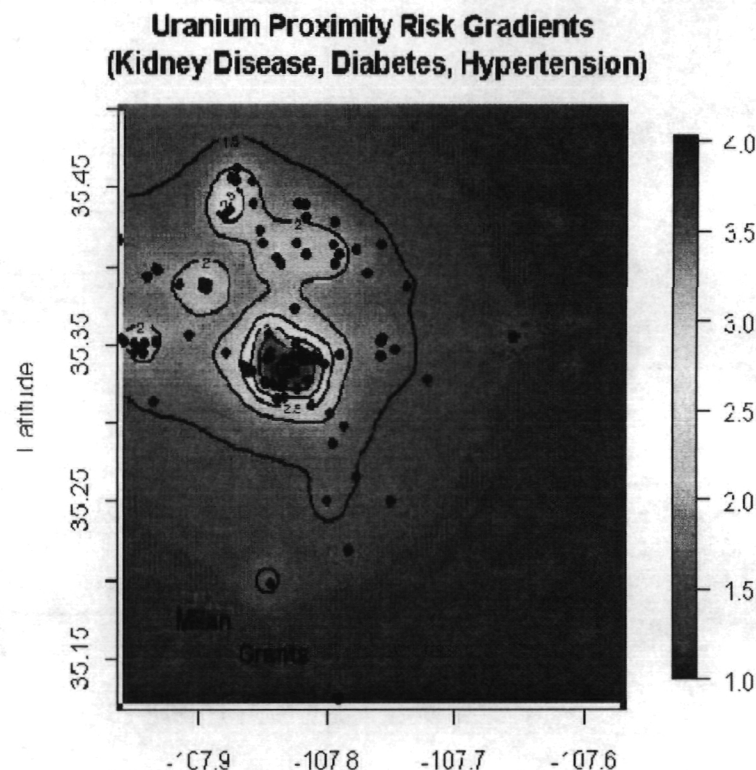
Urine uranium (n=22 only at this time)

Urine-Uranium Comparisons (ug U/g Cr)			
STUDY →	DiNEH Kidney Study (n=22)	NHANES (2001-2002)	NMDOH Biomonitoring
Participants →	Residents near mines	National survey	Volunteers
Median	0.0441	0.007	0.026
3 rd Quartile	0.0818	0.014	0.058
95 th %ile	0.3562	0.040	0.354



What Do DiNEH Results Tell Us About Other NM Communities?

- Current analysis is based on self-reported data for the DiNEH study area on Eastern Navajo *only*
- If these results are generally applicable, they may provide a significant predictor of disease in other communities in New Mexico
- Model validation more efficient process than model development
- For example, the map at right shows an illustration of the range of odds ratios that might be predicted for the San Mateo Basin communities
- *(NOTE: this is an illustration of uranium-proximity risk gradients based ONLY on location of abandoned mines, NOT weighted by surface area of the features as in the DiNEH predictors.)*



Black circles represent locations of mine features. Color scale on right indicates scale of increasing odds ratios for disease based on the number of mines only. Map shows a distinct region where odds ratios are increased more than 4-fold because of proximity to mines. Higher Ors reflect substantially higher density of features than in DiNEH study area.

What it has taken to get these results

- **>\$2.5 million in research support**
- **6 yrs of research design, data gathering, analysis**
- **Staff of 14 plus substantial in-kind support and collaboration**
- **Multidisciplinary technical/professional team**
 - **Toxicology, Navajo language/culture, geochemistry, hydrology, public health, mining/milling history, clinical care and laboratory analysis, statistical modeling, geospatial analysis, Bayesian analysis, exposure assessment, outreach and risk communication**
- **Collaboration with multiple agencies**
 - **Navajo Nation: NNEPA, NNAML, NNDOH, NNDWR**
 - **New Mexico: NMDOH, NMED, NMEMNR**
 - **US: USEPA, ATSDR, IHS, ACE**

Questions not yet addressed

- **Additional exposures from living in contaminated structures identified through 5-Year Plan**
 - Health risks associated with U plus decay chain radionuclides
 - Structure exposure adds to proximity exposures
 - Radon in homes may be primary toxicant (lung cancer)
 - Radium also identified
 - Need to evaluate multiple potential outcomes in those individuals
- **Outcomes of combined exposures (either by source or by toxicant)**
 - E.g. structures + proximity + drinking water; uranium + arsenic + mercury
- **Remainder of DiNEH Project scope**
 - Clinical assessments
 - Laboratory biomarker analyses
 - Follow-up on other potential disease endpoints
 - Autoimmune disease (link to U from DiNEH analysis and parallel to other metal exposures)
 - Cancers (continuing community concern, supported by in vitro laboratory work at AFFRI, in France, and NAU/U of A)
 - Reproductive and developmental outcomes (Shields et al., 1992)
- **Whether results generalize to other populations**

Acknowledgements

- **NIEHS for financial support**
- **Community Advisory Board**
 - Thomas Manning, Jean Whitehorse, Jay DeGroat, Ed Carlisle, Lynnea Smith, Herbert Enrico
- **UNM-HSC Community Environmental Health Program & Clinical and Translational Science Center**
 - Mallery Downs, R.N.; Miranda Cajero, B.C.H.; Bernadette Pacheco; Pat Leonard, R.N.; Glenn Stark; Gabriel Huerta, Ph.D.
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 - Harry Goldenberg, MD; Virgil Davis
- **Navajo Area IHS**
 - John Hubbard; Doug Peter, M.D.
- **UT-Houston Nephrology**
 - Donald Molony, M.D.
- **Southwest Research Information Center**
 - Chris Shuey, MPH, Sarah Adeky, Teddy Nez, Sandy Ramone
- **Students**
 - Jamie deLemos, Ph.D. Candidate - Tufts
 - Christine George, Ph.D. Candidate - Columbia
 - Tommy Rock, UNM Health Policy
- **Dartmouth**
 - Ben Bostick, Ph.D.
- **University of Arizona Cancer Center & Northern Arizona University**
 - Jani Ingram, Ph.D., Margaret Briebl, Ph.D.
- **Fernald Medical Monitoring Program**
 - Susan Pinney, Ph.D.
- **USEPA Region IX**
- **State of New Mexico Diagnostic Laboratory**
- **Navajo Nation EPA (Office of Drinking Water)**
- **Navajo Nation Division of Health**
- **Former Contributors:**
 - Bess Seschillie, Jeremy DeGroat, Sandy Ramone, Bernice Norton, Jerry Elwood, Harrison Gorman, Harris Arthur (in memoriam), Alda McCabe Margaret Menache, Ph.D., Alexis Kaminsky, Ph.D.; Eastern Navajo Health Board